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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,449

12/13/2005

James Edward Eyles

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,449	Applicant(s) EYLES ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-25 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Response to Office Action, received 15 April 2009, is acknowledged. Claim 28 has been amended.
2. Claims 17-25 and 28 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of the amendment of the claim.
4. The rejection of claims 17-19, 22-25 and 28 under 35 U.S.C. 103(a) as being unpatentable over Lowell et al (*Infection and Immunity*, 64(5):1706-1713, 1996) in view of (Zeng et al, *International Journal of Pharmaceutics*, 124:149-164, 1995) is withdrawn.

Applicants argue that Lowell et al fails to teach or suggest a formulation comprising a microencapsulated antigen or administration of aerosol compositions, but teaches the use of proteosomes comprising formalinized toxoid of staphylococcal enterotoxing B.

The examiner has considered applicants' argument concerning Lowell et al and finds it persuasive.

Rejections Maintained

5. The rejection of claims 17-25 and 28 under 35 U.S.C. 103(a) as being unpatentable over Eyles et al (*Vaccine*, 19:4732-4742, 2001) in view of (Zeng et al, *International Journal of Pharmaceutics*, 124:149-164, 1995) is maintained.

Applicants argue that while Eyles et al discloses the study of immune response in mice following nasal administration of a suspension of poly(lactide) microspheres loaded with recombinant *Y. pestis* V antigen, Eyles et al do not report any experimental data regarding

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protection of the animals following pathogen challenge. Eyles et al also cautions about valid concerns of the safety of aerosolization for the design of mucosal immunization.

Applicants argue that while Zeng et al discloses controlled delivery of therapeutic drugs to the lung in biodegradable microspheres, they do not teach or suggest delivery of microencapsulated antigens for the purpose of producing a protective immune response.

The examiner has considered applicants' arguments, but does not find them persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

At least one embodiment of the instant claims is a method of producing a protective immune response against a pathogen comprising administration to a lung of the mammal a protective amount of an aerosol comprising biodegradable microspheres of an average diameter of from 0.5 to 5 microns comprising a nonliving reagent.

As put forth in the original rejection, Eyles et al do teach a formulation of biodegradable microspheres recited in the instant claims and administration of said microspheres to the mucosal airways of mice, i.e., intranasal, with deposition of the microspheres throughout the respiratory tract (abstract) including bronchopulmonary deposition (abstract). They state that these studies support the tenet that, following an appropriate method of mucosal delivery, microparticles can translocate to tissues in the systemic compartment of the immune system and thence provoke immunological reactions therein.

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Thus, it would have been obvious to one of ordinary skill in the art to deposit the microspheres of Eyles et al into the lungs, i.e., bronchopulmonary deposition, utilizing an appropriate method of mucosal delivery, i.e., the aerosolization of Zeng et al.

Conclusion

6. Claims 17-25 and 28 are finally rejected.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

June 30, 2009